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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,576	09/24/2003	Dieter Hochrainer	1/1401	6795

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT PAPER NUMBER

3743

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,576

Applicant(s)

HOCHRAINER ET AL.

Examiner

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed, after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,9-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,9-14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et.al. (6,089,228).

Smith in a dry powder inhaler:

- with mouthpiece (32) for dispersing pharmaceutical drug formulations,
- having an auxiliary energy source (338, 390) in the form of a pressure medium system,
- with a device (342) for provisioning of a powder formulation, whereby upon activation of the pressure medium system (338) a gaseous pressure medium (20) released by the pressure medium system forms with the powder formulation an aerosol in such a way that the powder particles are present in dispersed form within the gaseous pressure medium, characterized in that provided in the inhaler is a Laval nozzle (at 14; because a laval nozzle is convergent-divergent nozzle (i.e., venturi-like), the nozzle of Smith is readable upon a Laval nozzle) through which the aerosol flows before leaving the inhaler (Figs. 1, 2).



FIG. 4A

With respect to claim 7, Smith discloses that the narrowest cross section of the nozzle is 100 μ m to 1500 μ m (Col. 14, lines 59-67).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 9, 10, 12-14, and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk et.al. (WO 90/07351).

Schenk in a inhaler discloses: a mouthpiece (20) for dispensing pharmaceutical drug formulations, having an auxiliary energy source in the form of a pressure medium system (12), with a device for provisioning (11) of a powder formulation, whereby upon activation of the pressure medium system a gaseous pressure medium (Fig. 1) released by the pressure medium system forms with the powder formulation an aerosol in such a way that the powder particles are present in dispersed form within the gaseous pressure medium, characterized in that provided in the inhaler is a Laval nozzle (at 18) through which the aerosol flows before leaving the inhaler (Figs. 1-4).

With respect to claim 7, Schenk discloses that the narrowest cross section of the Laval nozzle is 100 μ m to 1500 μ m, preferably 400 μ m to 800 μ m in diameter (page 8).

With respect to claim 9, Schenk discloses that the pressure medium system exhibits a pump (Figs. 1-4) that is connected to the surroundings and uses ambient air as the pressure medium.

With respect to claim 10, Schenk discloses that the pressure medium system includes a cartridge that stores the pressure medium (17).

With respect to claim 12, Schenk discloses air is provided as the pressure medium (page 3).

With respect to claim 13, Schenk discloses wherein the device for provisioning of the powder formulation is placed between the pressure medium system and the Laval nozzle in such a way that the pressure medium must pass through the device (Figs. 1-4).

With respect to claim 14, Schenk discloses a capsule filled with powder (page 6).

With respect to claim 16, Schenk discloses a multi-dose blister container (page 6).

With respect to claim 17, Schenk discloses a flow rate sensor (at 35) that generates an input signal for the pressure medium system.

With respect to claim 18, Schenk discloses an inlet channel (24) whereby inhalation of air is drawn in through the inlet channel and whereby a swirling flow of the inhalation air is created between the outlet section and the outlet of the mouthpiece.

With respect to claim 19, Schenk discloses wherein the Laval nozzle and an inlet channel (24) for the inhalation air are arranged in such a way that the aerosol flow

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leaving the Laval nozzle and the inhalation air are directed in opposite directions (Figs. 1-4).

With respect to claim 20, Schenk discloses that the Laval nozzle and an inlet channel (24) for the inhalation of air are arranged in such a way that the aerosol flow leaving the Laval nozzle and the inhalation air collide with each other at an angle (Figs. 1-4).

With respect to claim 21, Schenk discloses that the channel that guides the aerosol flow and the inlet channels for the inhalation air empty into a swirl chamber (at 17) whereby, the aerosol cloud is directed from the swirl chamber to the Laval nozzle.

Response to Arguments

Applicant's arguments filed 6/28/06 have been fully considered but they are not persuasive. Applicant arguments are not commensurate with the scope of the claims, applicant argues the gas plus medicament are mixed in the first stage and go through the different portions of the valve together, first there is no first stage claimed nor valve, also if one reviews Fig. 1 valve 5 is positioned prior to gas or medication thereby making it impossible for the gas and/or medication to travel through the valve. The device of Smith and Schenk is readable upon the claims as presented, therefore the rejection previously presented is being maintained. The 112 first paragraph rejection is being removed as the claims have been cancelled therefore making the rejection moot.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Teena Mitchell
Primary Examiner
Art Unit 3743
September 3, 2006

TKM